Mercury Medical
160 South Main St., Suite A
Middleton, MA 01949

K000073
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Section 11 510(k) Summary or Statement

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Mercury Medical is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Mercury Medical chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: **Mercury Medical Disposable Radiofrequency Cannula**

Owner/Operator: Mercury Medical
160 South Main Street, Suite A
Middleton, MA 01949
Registration number not yet assigned

Manufacturing Site: Precise-Pak
30 Centre Road
Sommersworth, NH 03878
Registration #1221631

Sterilization Site: Professional Contract Sterilization, Inc.
40 Myles Standish Blvd.
Taunton, MA 02780
Registration #1222313

Device Generic Name: Probe, Radiofrequency, Lesion

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (21 CFR 882.4725).

Predicate Devices: Radionics, Inc. TIC Cannula (preamendment), SMK-C (K870028), RSM-C (K963577) and RFK-DS (K980430) Cannulas

Baylis Medical Corp. RF Cannula (K972846)

Howmedica Liebenger RF Cannula (K# unknown)

Product Description:
The proposed Mercury Medical Disposable Radiofrequency Cannula consists of a stainless steel, Teflon coated cannula with a stainless steel stylet and hub. The cannula will be available with a straight or 15-degree curved tip, a 4mm or 10mm exposed tip, and in lengths ranging from 5-15cm.

Indications for Use:
The Mercury Medical Disposable Radiofrequency Cannula is indicated for use in radiofrequency (RF) heat lesion procedures for the relief of pain.

Performance Testing:
Substantial equivalence for the proposed Mercury Medical Disposable Radiofrequency Cannula is based solely on a comparison of materials, design, specifications and principle of operation as compared to the predicate devices. Therefore, there were no performance testing requirements for this submission.

Conclusion:
Based on the indications for use and technological/design characteristics, the Mercury Medical Disposable Radiofrequency Cannula has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2000

Mr. Matthew Nekoroski
President
Mercury Medical Products, Inc.
160 South Main Street, Suite A
Middleton, Massachusetts 01949

Re: K000073
Trade Name: Mercury Medical Disposable Radiofrequency Cannula
Regulatory Class: II
Product Code: GXI
Dated: January 7, 2000
Received: January 10, 2000

Dear Mr. Nekoroski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Mercury Medical
160 South Main St., Suite A
Middleton, MA 01949

510(k) Number (if known): K000073

Device Name: Mercury Medical Disposable Radiofrequency Cannula

Indications for Use:

The Mercury Medical Disposable Radiofrequency Cannula is indicated for use in radiofrequency (RF) heat lesion procedures for the relief of pain.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000073